

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

LAURENCE PARIS and INTERPHARM
DEVELOPMENT, S.A.,

Plaintiffs,

v.

R.P. SCHERER CORP., et al.,

Defendants.

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Civil No. 02-1044 (AET)

MEMORANDUM AND ORDER

THOMPSON, U.S.D.J.

This matter comes before the court pursuant to a hearing held on October 25, 2004, in accordance with Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The parties submitted pre-hearing and post-hearing briefs and presented oral argument in support of their respective positions. In this lawsuit, Plaintiffs assert infringement of claim 1 of their Patent No. 6,331,205 (the “‘205 patent”). The court is being asked to rule on the meaning of only one term in that claim: “gelling agent.”

BACKGROUND

Plaintiffs in this case are Dr. Laurence Paris (“Paris”), a French citizen with a Doctor of Pharmacy Degree, and Interpharm Development, S.A. (“Interpharm”), a company that allegedly owns certain of Dr. Paris’s intellectual property rights. Plaintiff Interpharm is incorporated in Panama and located in Switzerland.

Defendant R.P. Scherer Corporation¹ (“Scherer”) is a Delaware company with its headquarters in New Jersey. The dispute between the parties arises out of business dealings and contract agreements between Dr. Paris and Scherer. The contracts deal with the development of carrageenan-based capsule technology. Dr. Paris has developed technology which allows for capsules to be made without animal by-product ingredients, specifically without gelatin. Scherer formulates, develops, and manufactures drug delivery technologies and does substantial business making soft gelatin capsules. In 1997, the parties began doing business with one another wherein Scherer explored the possibility of manufacturing capsules using Paris’s formula for the capsules. In 1998, Dr. Paris applied for patent protection for improvements she made for the formula for gelatin-free capsules, as well as for the process and method for manufacturing those capsules using a heating and freezing process. The United States Patent and Trademark Office granted Paris’s’ application and issued the ‘205 patent. In 2001, prior to the issuance of the ‘205 patent, the parties entered into an exclusive license agreement whereby Scherer had all rights to the technology covered in the ‘205 patent application.

In late 2001, Scherer began marketing gelatin free capsules utilizing carrageenan without paying royalties to Plaintiffs. Plaintiffs allege that these capsules, but for the license agreement, infringe the ‘205 patent. Scherer contends that its capsules fall outside of the scope of the ‘205 patent, which only covers compositions that are made with a single “gelling agent.” It is the meaning of the term “gelling agent” that the parties now request the court to construe.

¹This Court dismissed all of Plaintiffs’ claims against Scherer’s parent corporation, Cardinal Health, Inc., in an Order dated October 15, 2002.

DISCUSSION

I. LEGAL STANDARD

Construction of a patent claim is a matter of law exclusively for the court. Markman, 52 F.3d at 979. While the court may utilize numerous sources for guidance in determining the proper construction of a claim, it is well-settled that the Court should consult the claim language, the patent specification and the prosecution history on record, which together constitute the “intrinsic evidence.” Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). “Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.” Id.

This court’s claim construction analysis must be guided by the Federal Circuit’s recent decision in Phillips v. AWH Corp., — F.3d —, 2005 WL 1620331 (Fed. Cir. Jul. 12, 2005) (en banc). In Phillips, the court emphasized the “‘bedrock principle’ of patent law” that “the claims of a patent define the invention to which the patentee is entitled the right to exclude.” 2005 WL 1620331, at *4 (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). To that end, the words used in a claim are generally given their ordinary and customary meaning. Id. at *5. The ordinary and customary meaning of a claim term “is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” Id. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. Id. This principle of patent law flows naturally from the recognition that inventors are usually persons who are skilled in the field of the invention, and are to whom the patent is addressed. Id.

Phillips emphasized that “the person of ordinary skill in the art is deemed to read the

claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” Id. In other words, a patent’s claims “do not have meaning removed from the context from which they arose.” Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir. 2001). Thus, while a court should consider the use of a term within the claim, and in the context of the patent’s other claims, the claims must be read in view of the specification, of which they are a part. Phillips, 2005 WL 1620331, at *7. The specification can “act[] as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.” Vitronics, 90 F.3d at 1582; see also Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1300 (Fed. Cir. 2004) (“Even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents.”) (citations omitted). Thus, the specification “is the single best guide to the meaning of a disputed term” and is often dispositive. Vitronics, 90 F.3d at 1582.

The prosecution history also plays an important role in claim interpretation, as it “contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims.” Vitronics, 90 F.3d at 1582. An analysis of the file history may include an examination of the prior art cited therein. Id. (citing Autogiro Co. of America v. United States, 384 F.2d 391, 399 (Fed. Cir. 1967) (“In its broader use as source material, the prior art cited in the file wrapper gives clues as to what the claims do not cover.”) (citations omitted)).

Although the Federal Circuit has emphasized the importance of intrinsic evidence in claim construction, it has also authorized district courts to consider extrinsic evidence which “consists of all evidence external to the patent and prosecution history, including expert and

inventor testimony, dictionaries, and learned treatises.” Markman, 52 F.3d at 980. However, while “extrinsic evidence may be useful to the court . . . it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” Phillips, 2005 WL 1620331, at *11. Thus, a district court is not “barred from considering any particular sources or required to analyze sources in any specific sequence, as long as those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence.” Id. at *16.

II. ANALYSIS

Claim 1 of the ‘205 patent states:

1. A viscous aqueous composition for making soft or hard capsules for aqueous and oily solutions, the composition comprising an aqueous medium and a single **gelling agent** consisting of an iota carrageenan, the concentration of the iota carrageenan being at least 5% of the aqueous medium, the composition further comprising at least one ion selected from the group consisting of the alkaline and alkaline earth ions.

(Pls.’ Opening Br., Ex. A, col. 5:54-61) (emphasis added). Plaintiffs contend that a “gelling agent” should be defined as “a substance which forms a continuous, three-dimensional network of the substance throughout the composition in a time frame relevant to capsule-making processes, i.e., by the time the capsule is formed.” Defendants contend that a gelling agent is “a polymer that contributes to the three-dimensional structure of a gel network.”

At the outset, the Court notes that the ‘205 patent does not explicitly define the term “gelling agent.” However, a person of ordinary skill in the art would define gelling agent in the context of the ‘205 patent rather than in a factual vacuum. Defendant’s expert Dr. Seib and Plaintiff’s expert Dr. Ziegler both agree that a substance can act as a gelling agent in some

circumstances and not in others.² In other words, a gelling agent is not defined by what it is, but by what it does. For this reason, something that could function as a gelling agent in an abstract case, may not function as a gelling agent in the ‘205 patent. The purpose of the ‘205 patent, is “to make pure carrageenan films for the manufacturing of hard and soft capsules . . . as well as a method for making the said film and soft capsules.” (Pls.’ Opening Br., Ex. A, col. 1:14-16.)

A. “Substance” or “Polymer”

Plaintiffs contend that a gelling agent should be described generally as a “substance,” while Defendants argue for the more specific term “polymer.” While it is clear that a single polymer, carrageenan, is acting as the gelling agent in the ‘205 patent, the prior art discloses situations where two polymers act as gelling agents in the manufacture of capsules. Thus, in the context of producing films for capsule manufacturing, the singular word “polymer” does not suffice to describe “gelling agent.” Further, there is no suggestion in the intrinsic or extrinsic evidence that only polymers can function as gelling agents. For these reasons, the Court will utilize Plaintiffs’ broader term “substance” rather than Defendants’ term “polymer.”

B. “Forms” or “Contributes To”

Plaintiffs argue that a gelling agent “forms” a gel network, while Defendants maintain that a gelling agent “contributes to” a gel network. A review of the patent’s intrinsic evidence shows that Defendants’ use of the term “contributes to” is too vague and broad, and could be interpreted to make the patent’s dependent claims inconsistent with claim 1’s “single gelling

² Defendants’ expert, Norman Stroud, argued that one looks at the process to see how to use a gelling agent, but not to define whether something is a gelling agent. Under this reasoning, starch would always be termed a gelling agent because it has the capability to form a gel under certain circumstances. However, this definition does not comport with the ‘205 patent, which identifies carrageenan as the sole gelling agent (claim 1), and also utilizes starch (claim 14).

agent” restriction. See Renishaw plc v. Marposs Societa’ per Anzioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998) (noting that a Court should not interpret an independent claim in a way that renders any of the dependent claims invalid). For example, claims 14 and 15 of the ‘205 patent allow for the addition of starch (a polymer) to the composition. In these claims, starch functions as a disintegrating agent, which could be said to “contribute” to the three-dimensional structure of the network. Thus, starch could be considered a gelling agent under Defendants’ definition, rendering claims 14 and 15 invalid in light of claim 1’s single gelling agent limitation.

Defendants argue that their use of the term “contributes to” is mandated by the patent specification, which designates mannans, galactomannans, and agar as “gelling agents,” (See Pls.’ Opening Br., Ex. A, col. 1:35-41), even though the former two polymers cannot form gels on their own. (Defs.’ Opening Br. 21.) However, contrary to Defendants’ contention, the use of the term “forms” does not automatically connote “on its own without the aid of another gelling agent.” As the specification makes clear, a gel network can be formed by one or more gelling agents. The patent’s reference to other gelling agents in connection with prior art demonstrates exactly the type of case where two gelling agents combine to form a gel network. (See, e.g., Defs.’ Hr’g Binder, Ex. 20, at 0016 (specifying that the capsule film is formed from agar “as the base to make a relatively strong network and including in that network” substances such as carrageenan)). Similarly, if mannans and galactomannans combine with another gelling agent to create a gel network, those polymers “form” part of the gel network that is created. While it is true that mannans and galactomannans can also be said to “contribute to” that gel network, as discussed above, the term “contribute to” is overbroad as it can also encompass polymers that do not form a gel network but associate with that network.

Consulting extrinsic evidence only supports the interpretation derived from the intrinsic evidence. The dictionary definitions cited to the Court by both parties lead to almost identical definitions: a gelling agent is something that produces or causes the effect of gelling. (See, e.g., Defs.’ Opening Br. at 19; Pls.’ Opening Br. at 21.) Further, neither party disputes that gelling agents produce three-dimensional gel networks.³ (See, e.g., Defs.’ Opening Br. at 19-20; Pls.’ Opening Br. at 22.) Thus, in accordance with the dictionary definitions provided by the parties, a gelling agent must “effect” or bring about a three-dimensional network, rather than just “affect” or influence a three-dimensional network. Correspondingly, Plaintiffs’ term “forms” more closely approximates “effects” and Defendants’ term “contributes to” approximates “affects.”

C. “Continuous Three-Dimensional Network” or “Three-Dimensional Network”

As discussed above, the parties agree that a three-dimensional network is produced by a gelling agent or agents. However, the Plaintiffs wish to add an additional characteristic to that network. Specifically, Plaintiffs note that, in order to form the carrageenan film used to produce capsules, the gelling agent must form a **continuous** three-dimensional network of the substance throughout the composition. Defendants, in contrast, argue that the three-dimensional gel network must be continuous on a molecular level (i.e. within its own gel phase) but need not be continuous on a macroscopic level (i.e. throughout the composition).

A person of ordinary skill in the art, reviewing the patent’s claims and specification, would conclude that the term “gelling agent” is used to describe the macroscopic composition. For example, patent claim 1 states: “A viscous aqueous **composition for making soft or hard**

³ The specific characteristics of that three-dimensional network, in the context of the ‘205 patent, are disputed, and are discussed in Section C, infra.

capsules for aqueous and oily solutions, the **composition comprising** an aqueous medium and a single gelling agent consisting of an iota carrageenan.” (Pls.’ Opening Br., Ex. A, col. 5:54-57) (emphasis added). The single gelling agent of iota carrageenan is discussed in terms of the composition for making soft or hard capsules that it creates. This “viscous aqueous composition” is the macroscopic substance that will be used to encapsulate “aqueous and oily solutions.” The “Summary of the Invention” likewise states that the carrageenans are “the one and single gelling agent **of the composition of the shell.**” (Pls.’ Opening Br., Ex. A, col. 1:55-57) (emphasis added). Again, the gelling agent is discussed in terms of its creation of the shell. Thus, the intrinsic evidence suggests that the term gelling agent must be considered in the context of creating a capsule shell rather than on a molecular level.

The extrinsic evidence corroborates this interpretation. Both Plaintiffs’ and Defendants’ experts acknowledge that there can be a secondary gel phase which is not continuous throughout the composition. (See, e.g., Defs.’ Hr’g Binder, Ex. 23, Figure 14B.) However, if a substance serves as a gelling agent for a secondary gel phase, which exists on the microscopic level, it does not mean that the substance also serves as a gelling agent for the macroscopic composition (the film used to create capsule shells). Both Plaintiffs’ expert, Dr. Ziegler, and Defendants’ expert, Dr. Seib, acknowledged during their testimony that, in the context of this patent, there must be at least one gelling agent that is continuous throughout the composition in order to hold the product (a film used to create capsule shells) together. Without a gelling agent that creates a continuous network (carrageenan in the ‘205 patent), the film cannot be formed.

D. “In a Time Frame Relevant to Capsule-Making Processes”

Finally, Plaintiffs seek to include the additional qualification “in a time frame relevant to

capsule-making process, i.e. by the time the capsule is formed” to the definition of gelling agent. Plaintiffs contend that “a skilled artisan would understand that the practicalities of capsule manufacturing imply a requirement that “gelling agents” exert their gelling function in a relatively short amount of time – on the scale of seconds or minutes.” (Pls.’ Opening Br. 26.)

Unlike the previous “continuous three-dimensional network” limitation, there is no basis for this limitation in the intrinsic record. Discussing the practicalities of commercial capsule manufacturing is outside the scope of this patent. Further, the seemingly simple requirement of gelling “by the time the capsule is formed” obscures significant debate about when capsule formation is complete, and/or when the capsule is “finished.” For these reasons, the Court declines to add any temporal phrasing to the definition of gelling agent.

For the foregoing reasons and for good cause shown,

It is on this 15th day of August 2005,

ORDERED that the term “gelling agent” in claim 1 of the ‘205 patent shall be construed in all future proceedings, pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), aff’d, 517 U.S. 370 (1996), as a substance which forms a continuous, three-dimensional network of the substance throughout the composition.

s/Anne E. Thompson

ANNE E. THOMPSON, U.S.D.J.